Indiana

R.E.S.P.E.C.T.

Indiana Reduces Early Sex and Pregnancy By Educating Children and Teens

Adolescent Pregnancy Prevention Initiative

Community Grant Program
October 1, 2005 – September 30, 2007
Application Packet

Sexual Abstinence Education Programs

Administered by Indiana State Department of Health Maternal and Children's Special Health Care Services



Purpose:

The Indiana State Department of Health, Maternal and Children's Special Health Care Services announces the availability of <u>Title V Section 510 Abstinence Education Program Grant</u> federal funds to support community-based educational efforts to provide sexual abstinence education as a strategy to prevent adolescent and out-of-wedlock pregnancies. Public Law 104-193, enacted August 22, 1996, added the Section 510 formula grant program to Title V of the Social Security Act. The purpose of Section 510 is to "enable the state to provide abstinence education, and at the option of the state, where appropriate, mentoring, counseling, and adult supervision to promote abstinence from sexual activity, with a focus on those groups most likely to bear children out of wedlock." Abstinence education is specifically defined in the law. (see Selection Criteria Section.)

Federal funding for the Abstinence Education Program Grant has been authorized for FY 2006. Funding for FY 2007 is pending, based on Congressional reauthorization of the Federal Section 510 Abstinence Education Program Grant.

This announcement directly addresses the <u>Healthy People 2010</u> National Health Objectives which focus on reducing pregnancies among adolescent females aged 15 to 17 years, increasing the proportion of adolescents who have never engaged in sexual intercourse, and increasing the proportion of adolescents who have received formal instruction on reproductive health issues.¹

With this announcement, the Indiana State Department of Health, Maternal and Children's Special Health Care Services is interested in partnering with local community organizations, schools, and agencies to implement educational programs which address locally determined priorities and needs.

Background:

Despite the recently declining teen pregnancy rates in the United States, 34 percent of teenage girls get pregnant at least once before they reach age 20, resulting in more than 820,000 teen pregnancies a year. At this level, the United States has the highest rate of teen pregnancy in the fully industrialized world. Eight in ten of these pregnancies are unintended and 79 percent are to unmarried teens.

In 2002, 9,701 Indiana females aged 19 years and under gave birth. Infants born to teenaged mothers, especially mothers under age 15 years, are more likely to suffer from low birth weight, neonatal death, and sudden infant death syndrome. The infants may be at greater risk of child abuse, neglect, and behavioral and educational problems at later stages.

Teen pregnancy is closely linked with poverty and single-parenthood. Seventy-nine percent of births to teens occur outside of marriage and 25 percent of teenage mothers have a second child within two years of their first. Less than one-third of teens who

begin their families before age 18 ever earn a high school diploma and only 1.5 percent earn a college degree by the age of 30.8 Each year the federal government alone spends about \$40 billion to help families that began with a teenage birth.9

Eligibility Requirements:

All public or private not-for-profit organizations and agencies are eligible to apply. Grants will be awarded to applicants who are determined to demonstrate the capability of providing the proposed services and commitment to meeting the statutory requirements. Partnerships among applicants from the same geographic area are encouraged.

Selection Criteria:

Programs funded must provide instruction consistent with abstinence education as defined in the "Personal Responsibility and Work Opportunity Reconciliation Act of 1996", P.L.104-193. Under this announcement, abstinence education is defined as "an educational or motivational program which:

- A. Has as its exclusive purpose, teaching the social, psychological, and health gains to be realized by abstaining from sexual activity;
- B. Teaches abstinence from sexual activity outside marriage as the expected standard for all school age children;
- C. Teaches that abstinence from sexual activity is the only certain way to avoid out-of-wedlock pregnancy, sexually transmitted diseases, and other associated health problems;
- D. Teaches that a mutually faithful monogamous relationship in context of marriage is the expected standard of human sexual activity;
- E. Teaches that sexual activity outside the context of marriage is likely to have harmful psychological and physical effects;
- F. Teaches that bearing children out-of-wedlock is likely to have harmful consequences for the child, the child's parents, and society;
- G. Teaches young people how to reject sexual advances and how alcohol and drug use increases vulnerability to sexual advances; and
- H. Teaches the importance of attaining self-sufficiency before engaging in sexual activity."

The Indiana State Department of Health, Maternal and Children's Special Health Care Services recognizes that varying needs and priorities of local communities will result in the development of programs with significant variation. As indicated in the Maternal and Child Health Bureau's Application Guidance the Abstinence Education Provision of the 1996 Welfare Law P.L. 104-193, it is not necessary to place equal emphasis on each element of the definition; however, a program may not be inconsistent with any aspect of the Section 510 abstinence education definition. The Indiana State Department of Health, Maternal and Children's Special Health Care Services will monitor grantees for compliance with the federal 8-point abstinence education definition.

Instruction using these federal funds must stress sexual abstinence until marriage. These federal funds may not be used to provide instruction regarding family planning, contraceptive methods, and/or disease risk-reduction methods. Information provided to adolescents who may be or become involved in sexual activity, which relates to reducing the risk of unintended pregnancy and disease, must be medically accurate and must be presented within the context that sexual abstinence until marriage is recommended. These federal funds may <u>not</u> be used for the provision of medical services or medical supplies. Grantees may not teach or promote religion or provide religious instruction in federally-funded programs. Funded programs must be accessible to the general public. (Appendix A)

Applicants must be familiar with the enclosed documents (Appendix B) in their entirety to ensure compliance with all applicable requirements:

| • | P.L.104-193 Section 510 | Sexual Abstinence Education Definition |
|---|-------------------------|--|
| • | P.L.104-193 Section104 | Services Provided by Charitable, Religious, or |
| | | Private Organizations |

Article 1 Sections 4 and 6 of the Indiana Constitution
 I.C. 20-8.1-7-21
 AIDS Information

• I.C. 20-8.1-7-21 AIDS Information
• I.C. 20-10.1-4-10 AIDS Instruction

• I.C. 20-10.1-4-11 Sexual Abstinence Education Instruction in

Accredited Schools

• I.C. 20-10.1-4-15 Student Non-Academic Personal

Analysis/Evaluation/Survey in the

Classroom Setting

 Maternal and Child Health Bureau <u>Abstinence Advisory #2: Funding of</u> <u>Religiously-Affiliated Organizations</u> (June 7, 2002)

Funding Availability:

These federal funds will be administered by the Indiana State Department of Health, Maternal and Children's Special Health Care Services, Judith A. Ganser, M.D., M.P.H., Medical Director. Approximately \$1,100,000 will be available (contingent upon notification from the Administration of Children and Families) for the Abstinence Education Program Grant Community Grant Program for a 24-month period. The awards will begin October 1, 2005.

Federal funding for the Abstinence Education Program Grant has been approved for FY 2006. Funding for FY 2007 is pending, based on Congressional reauthorization of the Federal Section 510 Abstinence Education Program Grant.

Awards will be granted for a total 24-month budget period including two (2) budget segments:

1st 12-month budget period October 1, 2005 - September 30, 2006 2nd 12-month budget period October 1, 2006 - September 30, 2007

Applicants may request up to \$25,000 for the 1st 12-month budget period and up to \$25,000 for the 2nd 12-month budget period. Funds from the 1st 12-month budget period will not be allowed to carry over into the 2nd 12-month budget period.

The Indiana State Department of Health is committed to serving the broadest statewide range of applicants possible. For this reason, individual applicants will be allowed total maximum Indiana RESPECT funding (federal and state) of \$25,000 per 12-month budget period. Applicants may choose to complete applications for both the Federal Sexual Abstinence Education funds and State Adolescent Pregnancy Prevention Education funds; however, an individual applicant agency will be eligible to receive total Indiana RESPECT grants (federal grant and state grant) equaling a maximum of \$25,000 per 12-month funding period. School buildings will be considered as individual applicants. The application period for State funding requests ended in May, 2005 for FY 2006 and FY 2007.

Applicants are required to provide a local match (cash and/or in-kind) of 30% for each budget period (maximum of \$7,500/year for \$25,000 grant/year).

Efforts will be made to award grants in all geographic areas of the state.

New Requirement of Program:

All funded programs will participate in program monitoring and evaluation by ISDH staff or contract staff designated by ISDH.

How to Apply:

An application packet is enclosed.

Inquiries:

All inquiries regarding the grant program should be addressed to:

Katherine Newland, M.P.H Adolescent Health Coordinator Indiana State Department of Health Maternal and Children's Special Care Health Services 2 North Meridian Street, Section 8C Indianapolis, Indiana 46204 317/233-1374 (Phone) 317/233-1300 (Fax) 1-800-761-1271, ext. 1374 Additional informational materials regarding sexual abstinence education research, models, and programs will be made available at a scheduled technical assistance meeting to be held at ISDH on Monday, July 25th at 1:00 PM. If an agency is not able to attend the technical assistance meeting, the materials may be requested from:

Kim Rief 317/233-1261 (Phone)
Administrative Assistant 317/233-1300 (Fax)
Indiana State Department of Health 1-800-761-1271, ext. 1261
Maternal and Children's Special
Health Care Services
2 North Meridian Street, Section 8C
Indianapolis, Indiana 46204

Information available on the World Wide Web:

- Sexual Abstinence Education Programs and National Data/Statistics www.teenpregnancy.org/links.htm
- Indiana Data/Statistics www.IN.gov/isdh/dataandstats/data_and_statistics.htm

Time Table:

(Contingent upon receipt of notification of award from the Administration of Children and Families)

Applications available: July 6, 2005

Technical Assistance July 25, 2005

Meeting

Applications submitted to ISDH/Maternal & Children's Special Health

Care Services postmarked by: August 17, 2005

Grant recipients notified by: September 20, 2005

Grant start date: October 1, 2005

References

¹U.S. Department of Health and Human Services. *Healthy People 2010: Understanding and Improving Health.* Second Edition Washington, D.C.: Government Printing Office, November 2000.

²National Campaign to Prevent Teen Pregnancy. (2004). <u>Factsheet: How is the 34% statistic calculated?</u> Washington, DC: Author.

³Henshaw, S.K. (2004). *U.S. Teenage Pregnancy Statistics with Comparative Statistics for Women Aged 20-24*. New York: The Alan Guttmacher Institute.

⁴Singh, S., & Darroch, J.E. (2000). Adolescent pregnancy and childbearing: Levels and trends in developed countries. *Family Planning Perspectives*, 32(1), 14-23.

⁵Ventura, S.J., Hamilton, BE, & Sutton, P.D. (2003). Revised Birth and Fertility Rates for the United States, 2000 and 2001. National Vital Statistics Reports 51(4).

⁶Indiana State Department of Health, Epidemiology Resource Center

⁷Teenpregnancy.org, Teen Pregnancy: Not Just Another Single Issue, 2002

⁸Maynard, R.A. (Ed.). (1996). *Kids Having Kids: A Robin Hood Foundation Special Report on the Costs of Adolescent Childbearing*. New York: The Robin Hood Foundation.

⁹Flinn, S.K., & Hauser, D. (1998). *Teenage Pregnancy: The Case for Prevention. An Analysis of Recent Trends and Federal Expenditures Associated with Teenage Pregnancy.* Washington, DC: Advocates for Youth.

¹⁰Kirby, D. *No Easy Answers: Research Findings on Programs to Reduce Teen Pregnancy.* Washington, D.C.: The National Campaign to Prevent Teen Pregnancy, 1997.

INSTRUCTIONS for completing the Indiana RESPECT (Indiana Reduces Early Sex and Pregnancy by Educating Children and Teens) Adolescent Pregnancy Prevention Initiative – Sexual Abstinence Education Programs application.

Introduction:

If a grant is awarded as the result of this application, the applicant organization becomes a grantee and assumes legal and financial accountability for the awarded funds and for the performance of the grant-supported activities. The applicant organization is responsible for verifying the accuracy, validity, and conformity with the most current institutional guidelines of all the administrative, fiscal, and scientific information in the application. Deliberate withholding, falsification, or misrepresentation of information could result in administrative actions such as disapproval of an application or, if approved, contract termination.

Format:

This application must be <u>single-spaced</u>, printed on one side only, on 8 1/2" X 11" paper, using standard black type (no smaller than 12-pitch) that can be photocopied. All pages and forms must be <u>numbered</u> sequentially. The application must be <u>unbound</u>. **DO NOT** include photographs, oversized documents, video or audiotapes, or materials that cannot be photocopied.

Unacceptable Applications:

An application will be deemed unacceptable if it is 1) post-marked after the submission deadline of 8/17/05, 2) incomplete, 3) illegible, 4) not prepared according to the instructions, 5) insufficient to permit an adequate review, or 6) does not address the stated **Healthy People 2010** objective(s).

Instructions for Completing Form 1, "ISDH Grant Application."

- **Item 1.** Title of Project: List proposed project.
- **Response to Specific Program Announcement:** Check the box marked "YES" and identify the title of the announcement as: Indiana RESPECT.
- **Name of Program Director:** Name the one person responsible to the applicant organization for the specified and technical direction of the project.
- **Item 3b. Position Title:** Use the title of the program director that is most relevant to the proposed project.
- **Item 3c. Degree(s):** Indicate academic and professional degrees.
- **Item 3d. Mailing Address:** Self-explanatory.
- **Item 3e. Telephone Number:** Self-explanatory.
- **Item 3f. FAX Number:** Self-explanatory.

- Human Subjects: Check the box marked "YES". If the project activities are exempt from the Department of Health and Human Services (DHHS) regulations regarding Human Subjects, insert the exemption number(s) corresponding to one or more of the six categories listed. (Appendix C) If the project activities involving human subjects are not exempt, the applicant agency must submit an Assurance of Compliance and certification of Institutional Review Board (IRB) approval.
- **Item 5.** Budget Period: Budget Period is October 1, 2005 September 30, 2007 (24 months)
- **Item 6.** Amount Requested: Amount requested for the categories of "Personnel", "Other Operating," and "Equipment" must equal the "Total Amount".
- **Item 7. Type of Organization:** Check the appropriate box.
- **Item 8.** Applicant Agency: Provide the name and address of the organization that will be legally responsible for the proposed project.
- Item 9a. Self-explanatory
- Item 9b. Self-explanatory
- Item 10a. Self-explanatory
- Item 10b. Self-explanatory
- Item 11a. Self-explanatory
- Item 11b. Self-explanatory
- Item 12 Self-explanatory

<u>Instructions for Completing Form 1a, "Adolescent Pregnancy Prevention Education Programs - Prevention Strategies."</u>

On the attached Form 1a, "Sexual Abstinence Education Programs - Prevention Strategies," check any/all of the prevention strategies the funded program will implement with Indiana RESPECT funds. Please do not substitute another format.

Indiana RESPECT

(Indiana <u>Reduces Early Sex and Pregnancy by Educating Children and Teens)</u> Adolescent Pregnancy Prevention InitiativeSexual Abstinence Education Programs

Narrative Application

Section 1: Proposal Summary (1 page) - 10 pts.

This summary will provide the reviewer a succinct and clear narrative of the proposal. The summary must:

- Identify the problem(s) to be addressed
- State the project objectives
- Include an overview of solutions (methods)
- Identify the target population(s) (including county (ies) served)
- Include specific services provided
- Include a copy (or excerpts) of proposed curriculum

Section 2: Applicant Agency (1/2 page) - 5 pts.

Complete the attached Form 1, "Indiana State Department of Health Grant Application" and Form 1a, "Adolescent Pregnancy Prevention Strategies." Please do <u>not</u> substitute another format.

Describe the applicant agency. Include:

- An agency statement of purpose
- A brief agency history of serving youth
- An explanation of how the project will be implemented within the structure of the applicant agency
- An explanation of how the project will be implemented within priorities of the local community

Section 3: Statement of Need (1/2 page) - 15 pts.

Describe the specific problem(s) or need(s) related to sexual abstinence education to be addressed by the project. This section represents the reasoning for the proposal and should:

- Be supported by evidence such as statistical data, surveys of community leaders and youth (e.g., local Step Ahead Council Needs Assessment data, local Education Agency data)
- Describe target populations (include characteristics and numbers)

Section 4: Outcome Objective(s) (Form 2) - 5 pts.

On the attached Form 2, "<u>Healthy People 2010</u> National Health Objectives," check the outcome objective(s) related to sexual abstinence education the project will address. Please do not substitute another format.

Section 5: Process Objectives(s) Narrative (2 pages) and Proposed Work Plan (Forms 3a and 3b) - 25 pts.

The <u>process objectives narrative</u> (2 pages) should describe the process objective(s) for the project. Process objectives typically focus on the achievement of major activities over the course of the funding period (e.g., clients to be served, training sessions to be provided - what, by whom, for whom, by when). In this description, <u>clearly</u> relate the project process objective(s) to the grant selection criteria identified on page 3 of the application packet in the section, "Selection Criteria."

In this section, also describe the involvement of the target audience(s) (youth, parents, community members) in the design, development, implementation, and assessment of the proposed project.

Use the attached Forms 3a and 3b, "Work Plan," to identify the work plan/activities to be completed to achieve each identified process objective(s); one process objective per form. Complete Form 3a for the process objectives to be October 1, 2005 – September 30, 2006. Complete Form 3b for the process objectives to be completed October 1, 2006 – September 30, 2007. Please do <u>not</u> substitute another format. The activities should:

- Be logically related to needs and outcome objectives
- Be linked to specific process objectives
- Be easily understood
- Be presented in a logical step-by-step manner
- Identify responsible staff
- Identify target populations
- Indicate a time (date) when the activities will be achieved
- Be achievable in the funding period and within available resources

Section 6: Reporting Requirements/Evaluation Plan (1 page) - 5 pts.

Discuss project methods of data collection, data reporting, and measurement of:

- The completion of project activities
- The achievement of project process objective(s) (e.g., # of persons served/# of trainings provided)
- If possible, the achievement of <u>Healthy People 2010</u> National Health Objectives outcome objective(s) as identified in Form 2 (e.g., school/local/county adolescent birth incidence, pre/post assessments)

Indicate the program data related to the process objectives (e.g., # of persons served/# of trainings provided) to be collected during the program contract period and identify the person responsible for data collection and reporting. Submission of data is a requirement for Indiana State Department of Health, Maternal and Children's Special Health Care Services grantees.

Section 7: Staff (1/2 page) - 10 pts.

Describe the relevant education, training, and work experience of the project staff, which will enable them to successfully develop, implement, and evaluate the project or provide curriculum vitae/resume for project staff.

Section 8: Budget (Forms 4a and 4b) and Budget Narrative (2 pages) - 15 pts.

The budget is an estimate of what the project will cost. The Indiana State Department of Health, Maternal and Children's Special Health Care Services supports reasonable and necessary costs for grants within the scope of the approved projects. <u>Allowable</u> costs may include planning and evaluation, salaries, training, educational materials, educational equipment (infant simulators, videos, displays, models) media activities, instate travel (.34 cents/mile), incentives, and consultant fees. <u>Non-allowable</u> costs include food, out-of-state travel, and general equipment and computer equipment (hardware and software) for the maintenance of the applicant agency.

Complete Form 4a for the project budget for October 1, 2005 – September 30, 2006. Complete Form 4b for the project budget for October 1, 2006 – September 30, 2007. Please do not substitute a different format.

In the column marked, "ISDH Request," indicate the <u>cash</u> amount of Indiana RESPECT funds requested.

In the column marked, "Local Contribution/Other funds," indicate the total local contribution (cash and/or in-kind) the applicant agency would expend for the proposed program. This local contribution could include salaries, educational materials, educational equipment (infant simulators, videos, displays, models) media activities, instate travel, incentives, consultant fees, or any expenses directly related to the proposed program. Applicants are required to provide a minimum local match (cash and/or in-kind) of 30% for each budget period (maximum of \$7,500/year for \$25,000 grant/year).

The <u>budget narrative</u> (2 pages) must include a justification for <u>each</u> line item (line #1 - line #7 on Forms 4a & 4b). Each narrative statement should describe the specific item, how the specific item relates to the project, and how the amount shown in the budget was derived. Cash and/or in-kind local contributions should be identified by source and amount. Please include a separate budget narrative for Budget Period #1 October 1, 2005 – September 30, 2006 and Budget Period #2 October 1, 2006 – September 30, 2007.

Section 9: Endorsements (Attach) - 10 pts.

Provide a minimum of three (3) <u>current</u> letters of collaboration describing the collaborations that will occur between the project and other community organizations to implement the proposed program. (i.e., schools, community organizations, youth serving organizations)

Submission:

- Application must be postmarked by August 17, 2005.
- Please identify the applicant agency at the top of each page of the application
- Submit one original and three copies of the application to:

Kim Rief Indiana State Department of Health Maternal and Children's Special Health Care Services 2 North Meridian Street, Section 8-C Indianapolis, IN 46204

INDIANA STATE DEPARTMENT OF HEALTH GRANT APPLICATION

Follow Instructions Carefully

| 1 Chou mondene Caronany | | | | | | | | |
|---|--|--|--|--|--|--|--|--|
| 1. Title of Project | | | | | | | | |
| 2. Response to Specific Program Announcement | No Yes (if "Yes" state announcement title) | | | | | | | |
| 3a. Name of Program Director | 3b. Position Title 3c. Degrees | | | | | | | |
| 3d. Mailing Address | 3e. Telephone (Area Code, Number, & Extension) | | | | | | | |
| | 3f. FAX No. | | | | | | | |
| 4. Human Subjects No Yes (if "Yes" Exemption Number) | | | | | | | | |
| 5. Budget Period: From October 1, 2005 through | n September 30, 2007 | | | | | | | |
| 6. Amount Requested | 7. Type of Organization | | | | | | | |
| \$ Personnel | ,, | | | | | | | |
| \$ Other Operating | Public State Local | | | | | | | |
| \$ Equipment | | | | | | | | |
| | Private Nonprofit | | | | | | | |
| \$ Total Amount | | | | | | | | |
| 8. Applicant Agency Name Federal ID Number | | | | | | | | |
| Name | I ederal ib Number | | | | | | | |
| Address (Street, City, State, and Zip Code) | | | | | | | | |
| 9a. Chief Administrative Officer (type name) | 9b. Phone (Area Code, Number & Extension) | | | | | | | |
| 10a. Official Custodian of Funds (type name) | 10b. Phone (Area Code, Number & Extension) | | | | | | | |
| 11a. Person authorized to make legal and contractual agreement for the applicant agency (Type name & write signature) | 11b. Title | | | | | | | |
| TYPE | | | | | | | | |
| SIGNATURE | | | | | | | | |
| 12. Program Director Assurance: Signature | | | | | | | | |
| I agree to accept responsibility for the conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application. | | | | | | | | |

Indiana RESPECT Adolescent Pregnancy Prevention Initiative Adolescent Pregnancy Prevention Education Programs Prevention Strategy (ies)

Please indicate which of the following adolescent pregnancy prevention strategy (ies) the proposed project will implement with Indiana RESPECT funds:

| Youth Instruction | | Yo | uth Life Options Program |
|-------------------|--|-----------|--|
| | School Class Room/Small Group | | Family Life/Sexuality Education |
| | School Assembly | | Educational Tutoring/Mentoring |
| | Community-based Small Group | | Employment and Career Training |
| | Community-based Assembly | | Post-Secondary Education Opportunities |
| | (Fairs/Rallies/Forums) | | Creative Self-Expression |
| | | | Mental Health Services |
| | | | Medical Health Services (using local/in- kind contribution) |
| | | | |
| | | | |
| <u>Yo</u> | uth Development | <u>Ad</u> | lult/Community Development Parent Education |
| | Youth/Peer Educators | | Materials/Workshop |
| | Youth-Led Conference/Events | | Teacher/Professional Materials/Training |
| | Youth Mentoring (Adult to Youth) | | Community Events |
| | Youth Mentoring (Youth to Youth) | _ | (Fairs/Rallies/Forums) |
| | Youth Community Service/ Volunteering | | Media Outreach (TV/Radio/Newspapers/Newsletters/ Billboards) |
| | | | |
| | | | |

Indiana RESPECT Adolescent Pregnancy Prevention InitiativeSexual Abstinence Education Programs Healthy People 2010 National Health Objectives

Please indicate which of the following Healthy People 2010 outcome objective(s) the project will address:

9.7 Reduce pregnancies among adolescent females aged 15-17 years.

9.8 Increase the proportion of adolescents who have never engaged in sexual intercourse before age 15 years.

9.9 Increase the proportion of adolescents aged 15 to 17 years who have never engaged in sexual intercourse.

9.11 Increase the proportion of young adults who have received formal instruction before turning age 18 years on reproductive health issues, including all of the following topics: abstinence, birth control methods, safer sex to prevent HIV, and prevention of sexually transmitted diseases.

7.2 Increase the proportion of middle, junior high, and senior high schools that provide school health education to prevent health problems in the following areas: unintentional injury; violence; suicide; tobacco use and addiction; alcohol and other drug use; unintended pregnancy, HIV/AIDS, and STD infection; unhealthy dietary patterns; inadequate physical activity; and environment health.

(One Process Objective per page, duplicate as needed)

Indiana RESPECT Adolescent Pregnancy Prevention InitiativeSexual Abstinence Education Programs Work Plan October 2005 – September 2006

| Project Title: Check HP2010 Objective(s): 9.79.89.99.117.2 Process Objective: | | | | | County: Estimated Unduplicated Clients To Be Served: Youth: Parents/Adults: Professionals: | | | | | | | | | | |
|---|-----------|----------|----------|----------|--|----------|----------|----------|----------|----------|-----------|-----------|-----------|--------------------------------|-----------------|
| | | | | | | | MON | ITHS | | | | | | | |
| Tasks | Staff | Oct 1 | Nov 2 | Dec 3 | Jan 4 | Feb 5 | Mar 6 | Apr 7 | May 8 | Jun 9 | Jul 10 | Aug 11 | Sep 12 | Anticipated Completion Date | Completion Date |
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| METHOD (S) TO E | VALUATE O | UTCO | ME A | ND/O | R PR | OCES | SS OF | BJEC | TIVES | S: | | | | | |

Indiana RESPECT Adolescent Pregnancy Prevention InitiativeSexual Abstinence Education Programs Work Plan October 2006 – September 2007

| Tasks Staff 1 2 3 | | | County: Estimated Unduplicated Clients To Be Served: Youth: Parents/Adults: Professionals: | | | | | |
|--------------------------------------|----------------------|----------------------|--|--|-----------------|--|--|--|
| | MON | NTHS | | | | | | |
| | Jan Feb Mar 4 5 6 | Apr May Jun 7 8 9 | Jul Aug Se 10 11 12 | | Completion Date | | | |
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| METHOD(S) TO EVALUATE OUTCOME AND/OR | PROCESS OB | BJECTIVES: | | | | | | |

(One Process Objective per page, duplicate as needed)

Indiana RESPECT Adolescent Pregnancy Prevention InitiativeSexual Abstinence Education Programs Proposed Budget October 2005 – September 2006

| Project Name: | Budget Period: | From: <u>10/1/05</u> to | o: <u>9/30</u> |
|---|---------------------------|--|----------------|
| Category | Total Project Costs | Local Contribution/ Other Funds | IS Req |
| PERSONNEL (include fringes) | | | |
| OTHER OPERATING EXPENSES | | | |
| Consumable Supplies (includes postage) | | | |
| Travel (mileage, per diem, registration fees) | | | |
| Rental and Utilities (includes telephone) | | | |
| Consultant & Contractual Services | | | |
| Other Expenditures | | | |
| EQUIPMENT (allowable equipment defined p. 11) | | | |
| TOTAL BUDGET | | | |

Indiana RESPECT Adolescent Pregnancy Prevention InitiativeSexual Abstinence Education Programs Proposed Budget October 2006 - September 2007

| Project Name: | Puda | ot Dariad | Erom: | 10/1/06 to: | 0/30/0 |
|----------------------|------|-------------|---------|-------------|----------|
| Project Name. | budy | jet Periou. | FIOIII. | 10/1/00 to. | <u> </u> |

| | Category | Total Project Costs | Local Contribution/ Other Funds | ISDH Request |
|-----|---|---------------------------|--|-----------------|
| (1) | PERSONNEL (include fringes) | | | |
| | OTHER OPERATING EXPENSES | | | |
| (2) | Consumable Supplies (includes postage) | | | |
| (3) | Travel (mileage, per diem, registration fees) | | | |
| (4) | Rental and Utilities (includes telephone) | | | |
| (5) | Consultant & Contractual Services | | | |
| (6) | Other Expenditures | | | |
| (7) | EQUIPMENT (allowable equipment defined p.11) | | | |
| | TOTAL BUDGET | | | |

APPENDIX A

| FEDERAL (includes State match) | STATE |
|---|---|
| SEXUAL ABSTINENCE EDUCATION PROGRAMS | ADOLESCENT PREGNANCY PREVENTION EDUCATION PROGRAMS |
| SEXUAL ABSTINENCE UNTIL MARRIAGE | SEXUAL ABSTINENCE THROUGHOUT ADOLESCENT YEARS |
| NO INSTRUCTION RE: FAMILY PLANNING CONTRACEPTIVE METHODS DISEASE RISK-REDUCTION METHODS | MAY INCLUDE INSTRUCTION RE: FAMILY PLANNING CONTRACEPTIVE METHODS DISEASE RISK-REDUCTION METHODS (LOCAL DECISION) |
| NO MEDICAL SERVICESNO MEDICAL SUPPLIES | NO MEDICAL SERVICESNO MEDICAL SUPPLIES |
| NO PROMOTION OF RELIGION/RELIGIOUS INSTRUCTION | NO PROMOTION OF RELIGION/RELIGIOUS INSTRUCTION |

P.L.104-193 WELARE REFORM ACT – SEXUAL ABSTINENCE EDUCATION

Sec. 510. [42 U.S.C.710] (a) For the purpose described in subsection (b), the Secretary shall, for fiscal year 1998 and each subsequent fiscal year, allot to each State which has transmitted an application for the fiscal year under section 505(a) an amount equal to the product of –

- (1) the amount appropriated in subsection(d) for the fiscal year; and the percentage determined for the State under section 502(c)(1)(B)(ii)
- (b)(1) The purpose of an allotment under subsection (a) to a State is to enable the State to provide abstinence education, and at the option of the State, where appropriate, mentoring, counseling, and adult supervision to promote abstinence from sexual activity, with a focus on those groups which are most likely to bear children out-of-wedlock
 - (2) For purposes of this section, the term "abstinence education" means an educational or motivational program which
 - (A) has as its exclusive purpose, teaching the social, psychological, and health gains to be realized by abstaining from sexual activity;
 - (B) teaches abstinence from sexual activity outside marriage as the expected standard for all school age children;
 - (C) teaches that abstinence from sexual activity is the only certain way to avoid out-of-wedlock pregnancy, sexually transmitted diseases, and other associated health problems;
 - (D) teaches that a mutually faithful monogamous relationship in context of marriage is the expected standard of human sexual activity;
 - (E) teaches that sexual activity outside of the context of marriage is likely to have harmful psychological and physical effects:
 - (F) teaches that bearing children out-of-wedlock is likely to have harmful consequences for the child, the child's parents, and society;
 - (G) teaches young people how to reject sexual advances and how alcohol and drug use increases vulnerability to sexual advances; and
 - (H) teaches the importance of attaining self-sufficiency before engaging in sexual activity.
- (c)(1) Section 503, 507, and 508 apply to allotments under subsection (a) to the same extent and in the same manner as such sections apply to allotments under section 502(c).
- (2) Section 505 and 506 apply to allotments under subsection (a) to the extend determined by the Secretary to be appropriated.
- (d) For the purpose of allotments under subsection (a), there is appropriated, out of any money in the Treasury not otherwise appropriated, an additional \$50,000,000 for each of the fiscal years 1998 through 2002. The appropriation under the preceding sentence for a fiscal year is made on October 1 of the fiscal year.

 P.L.104-193 WELFARE REFORM ACT – SERVICES PROVIDED BY CHARITABLE, RELIGIOUS, OR PRIVATE ORGANIZATIONS

Sec. 104 SERVICES PROVIDED BY CHARITABLE, RELIGIOUS, OR PRIVATE ORGANIZATIONS

- (a) IN GENERAL -
- (1) STATE OPTIONS—A State may -
 - (A) administer and provide services under the programs described in subparagraph (A) and (B)(i) of paragraph (2) through contracts with charitable, religious, or private organizations; and
 - (B) provide beneficiaries of assistance under the programs described in subparagraphs (A) and (B)(ii) of paragraph (2) with certificates, vouchers, or other forms of disbursement which are redeemable with such organizations.
- (2) PROGRAMS DESCRIBED—The programs described in this paragraph are the following programs:
 - (A) A State program funded under part A of title IV of the Social Security Act (as amended by section 103(a) of this Act).
 - (B) Any other program established or modified under title I or II of this Act, that—
 - (i) permits contracts with organizations; or
 - (ii) permits certificates, vouchers, or other forms of disbursement to be provided to beneficiaries, as a means of providing assistance.
 - (b) RELIGIOUS ORGANIZATIONS—The purpose of this section is to allow States to contract with religious organizations, or to allow religious organizations to accept certificates, vouchers, or other forms of disbursement under any program described in subsection (a)(2), on the same basis as any other nongovernmental provider without impairing the religious character of such organizations, and without diminishing the religious freedom of beneficiaries of assistance funded under such program.
 - (c) NONDISCRIMINATION AGAINST RELIGIOUS ORGANIZATIONS—In the event a State exercises its authority under subsection (a), religious organizations are eligible, on the same basis as any other private organization, as contractors to provide assistance, or to accept certificates, vouchers, or other forms of disbursement, under any program described in subsection (a)(2) so long as the programs are implemented consistent with the Establishment Clause of the United States Constitution. Except as provided in subsection (k), neither the Federal Government nor a State receiving funds under such programs shall discriminate against an organization which is or applies to be a contractor to provide assistance, or which accepts certificates, vouchers, or other forms of disbursement, on the basis that the organization has a religious character.
 - (d) RELIGIOUS CHARACTER AND FREEDOM-
- (1) RELIGIOUS ORGANIZATIONS—A religious organization with a contract described in subsection (a)(1)(A), or which accepts certificates, vouchers, or other forms of disbursement under subsection (a)(1)(B), shall retain its independence from Federal, State,

and local governments, including such organization's control over the definition, development, practice, and expression of its religious beliefs.

- (2) ADDITIONAL SAFEGUARDS—Neither the Federal Government nor a State shall require a religious organization to—
 - (A) Alter its form of internal governance; or
 - (B) Remove religious art, icons, scripture, or other symbols; in order to be eligible to contract to provide assistance, or to accept certificates, vouchers, or other forms of disbursement, funded under a program described in subsection (a)(2).
 - (e) RIGHTS OF BENEFICIARIES OF ASSISTANCE—
- (1) IN GENERAL—If an individual described in paragraph (2) has an objection to the religious character of the organization or institution from which the individual receives, or would receive, assistance funded under any program described in subsection (a)(2), the State in which the individual resides shall provide such individual (if otherwise eligible for such assistance) within a reasonable period of time after the date of...that is accessible to the individual and the value of which is not less than the value of the assistance which the individual would have received from such organization.
- (2) INDIVIDUAL DESCRIBED—An individual described in this paragraph is an individual who receives, applies for, or requests to apply for, assistance under a program described in subsection (a)(2).
 - (f) EMPLOYMENT PRACTICES—A religious organization's exemption provided under section 702 of the Civil Rights Act of 1964 (42 U.S.C.2000e-1a) regarding employment practices shall not be affected by its participation in, or receipt of funds from, programs described in subsection (a)(2).
 - (g) NONDISCRIMINATION AGAINST BENEFICIARIES—Except as otherwise provided in law, a religious organization shall not discriminate against an individual in regard to rendering assistance funded under any program described in subsection (a)(2) on the basis of religion, a religious belief, or refusal to actively participate in a religious practice.
 - (h) FISCAL ACCOUNTABILITY—
- (1) IN GENERAL—Except as provided in paragraph (2), any religious organization contracting to provide assistant funded under anyu program described in subsection (a)(2) shall be subject to the same regulations as other contractors to account in accord with generally accepted auditing principles for the use of such funds provided under such programs.
- (2) LIMITED AUDIT—If such organization segregates Federal funds provided under such programs into separate accounts, then only the financial assistance provided with such funds shall be subject to audit.
 - (i) COMPLIANCE—Any party which seeks to enforce its rights under this section may assert a civil action for injunctive relief exclusively in an appropriate State court against the entity or agency that allegedly commits such violation.
 - (j) LIMITATIONS OF USE OF FUNDS FOR CERTAIN PURPOSES—No funds provided directly to institutions or organizations to provide services and administer programs under subsection (a)(1)(A) shall be expended for sectarian worship, instruction, or proselytization.

- (k) PREEMPTION—Nothing in this section shall be construed to preempt any provision of a State constitution or State statute that prohibits or restricts the expenditure of State funds in or by religious organizations.
- Article I Section 4 of the Indiana Constitution provides that: "No preference shall be given, by law, to any creed, religious society, or mode of worship; and no person shall be compelled to attend, erect, or support any place of worship, or to maintain any ministry against his consent".
- Article I Section 6 of the Indiana Constitution provides that: "No money shall be drawn from the treasury, for the benefit of any religious or theological institution."
- I.C.20-8.1-7-21 AIDS INFORMATION; CONTENTS; CONSENT TO DISTRIBUTION
 - Sec.21. (a) The state board of education shall provide information stressing the moral aspects of abstinence from sexual activity in any literature that it distributes to schoolchildren and young adults concerning available methods for the prevention of acquired immune deficiency syndrome (AIDS). Such literature must state that the best way to avoid AIDS is for young people to refrain from sexual activity until they are ready as adults to establish, in the context of marriage, a mutually faithful monogamous relationship.
 - (b) The state board of education may not distribute AIDS literature described in subsection (a) to schoolchildren without the consent of the governing body of the school corporation the schoolchildren attend. As added by P.L.197-1987, Sec.2.

I.C.20-10.1-4-10 AIDS INSTRUCTION

- Sec.10. (a) Each school corporation shall include in its curriculum instruction concerning the disease known as acquired immune deficiency syndrome (AIDS) and shall integrate this effort to the extent possible with instruction on other dangerous communicable diseases.
- (b) A school corporation shall consider the recommendations of the AIDS advisory council (as established in IC 20-8.1-11) concerning community standards on the content of the instruction, the manner in which the information is presented, and the grades in which it is taught.
- (c) Literature that is distributed to school children and young adults under this section must include information required by IC 20-8.1-7-21.
- (d) The department, in consultation with the state department of health, shall develop AIDS educational materials. The department shall make the materials developed under this section available to school corporations. As added by P.L.123-1988, Sec.21. Amended by P.L.2-1992, Sec.725.

I.C.20-10.1-4-11 SEX EDUCATION TO EMPHASIZE ABSTINENCE AND MONOGAMY

- Sec.11. Throughout instruction on human sexuality or sexually transmitted diseases, an accredited school shall:
 - (1) teach abstinence from sexual activity outside of marriage as the expected standard for all school age children;

- (2) include that abstinence from sexual activity is the only certain way to avoid out-of-wedlock pregnancy, sexually transmitted diseases, and other associated health problems; and
- (3) include that the best way to avoid sexually transmitted diseases and other associated health problems is to establish a mutually faithful monogamous relationship in the context of marriage. As added by P.L.134-1988, Sec. 3.

- I.C.20-10.1-4-15 ACCESS TO MATERIALS RELATING TO PERSONAL ANALYSIS, EVALUATION, OR SURVEY OF STUDENTS; CONSENT FOR PARTICIPATION
- Sec.15. (a) A school corporation shall make available for inspection by the parents or quardians of a student any instructional materials, including:
 - (1) teachers' manuals;
 - (2) student texts;
 - (3) films or other video materials:
 - (4) tapes; and
 - (5) other materials;

used in connection with a personal analysis, an evaluation, or a survey described in subsection (b).

- (b) A student shall not be required to participate in a personal analysis, an evaluation, or a survey that is not directly related to academic instruction and that reveals or attempts to affect the student's attitudes, habits, traits, opinions, beliefs, or feelings concerning:
 - (1) political affiliations;
 - (2) religious beliefs or practices;
 - (3) mental or psychological conditions that may embarrass the student or the student's family:
 - (4) sexual behavior or attitudes;
 - (5) illegal, antisocial, self-incriminating, or demeaning behavior;
 - (6) critical appraisals of other individuals with whom the student has a close family relationship;
 - (7) legally recognized privileged or confidential relationships, including a relationship with a lawyer, minister, or physician; or
 - (8) income (except as required by law to determine eligibility for participation in a program or for receiving financial assistance under a program);

without the prior consent of the student (if the student is an adult or emancipated minor) or the prior written consent of the student's parent or guardian (if the student is an unemancipated minor). A parental consent form for such a personal analysis, evaluations, or survey shall accurately reflect the contents and nature of the personal analysis, evaluation, or survey shall accurately reflect the contents and nature of the personal analysis, evaluation, or survey.

- (c) The department and the governing body shall give parents and students notice of their rights under this section.
 - (d) The governing body shall enforce this section. As added by P.L.204-1995, Sec.1.

Maternal and Child Health Bureau

Abstinence Advisory #2 June 7, 2002

Faith-based and community-based organizations are eligible to apply for Federal Abstinence Education Grant funding under the Maternal and Child Health Bureau's (MCHB) Special Projects of Regional and National Significance (SPRANS) Community-Based Abstinence Education Project Grant program, or such entities can participate as section 510 Abstinence Education State block grant sub-recipients. Please note, however, that no funds provided through either of these MCHB-funded abstinence programs may be expended for sectarian instruction, worship, prayer, or proselytization. If a religious organization offers such activities, they must be voluntary for the individuals receiving such services and offered separately from the MCHB-funded program. A MCHB-funded abstinence program cannot discriminate in providing abstinence education to an individual on the basis of religion, a religious belief, or a refusal to hold a religious belief. All curricula and educational materials for use in the MCHB-funded abstinence programs must not violate these restrictions on sectarian activities. Further guidance is provided in the attached Questions and Answers.

Maternal and Child Health Bureau

Abstinence Advisory #2

Ouestions and Answers

(1) Question: An MCHB-funded abstinence program is invited to present a program to adolescents attending a church-affiliated summer camp or school. Does this present a problem?

Answer: No. MCHB-funded programs should handle requests for abstinence education presentations in an evenhanded fashion, which neither discriminates against, nor favors, religion, a particular religious doctrine or affiliation, or non-religion (secular). Program education should be offered in a religiously neutral fashion, and decisions about where to offer classes should be made on program relevant criteria such as efficiency, need, public requests, or geographic balance rather than on any religion-related criteria.

(2) Question: A religiously affiliated grantee presents an abstinence class in an organization, like a shelter, which provides a variety of services for teens. Every day at a certain time, a message is announced over the loudspeaker that a worship service is being held in the chapel for anyone who cares to attend. Attendance is voluntary, for both abstinence students and others at the shelter. Neither the cost of the room nor the salary of

the leader of the service is paid for with MCHB abstinence funds. Does this present a problem?

Answer: No, it does not present a problem since attendance is voluntary and neither the cost of the room nor the salary of the service leader is paid for with MCHB abstinence funds.

(3) Question: An organization, which provides MCHB-funded abstinence education, also operates a residential care or prevention program, which provides shelter and a variety of services for teens. The organization, which sponsors the MCHB-funded abstinence class, makes religious counselors available for the abstinence students and others at the shelter. The counselors are not paid for with MCHB abstinence funds. They do not see abstinence students unless the students specifically request spiritual counseling. Does this present any problem?

Answer: No, as long as the counseling is requested voluntarily by the student, the counseling is not paid for with MCHB abstinence funds, and the counseling is performed at some time or place other than at the same time and location as the MCHB-funded abstinence education.

(4) Question: An MCHB-funded abstinence program is provided in a facility, which houses a library with many types of books, including some of a specific religious nature, such as Bibles and prayer books. These books were not purchased with MCHB abstinence funds. Does this present any problem?

Answer: No. It would be a problem only if the instructors during the MCHB-funded abstinence education class urged students to read the materials.

(5) Question: May a MCHB-funded abstinence program refer students to religiously affiliated service providers?

Answer: Yes. Referrals to other providers in the Section 510 Abstinence Education Program should be made in response to participant requests and not at the suggestion of the Section 510 or Special Projects of Regional and National Significance (SPRANS) Abstinence Education program provider. If a program participant requests such referral information and the religiously affiliated provider is the best referral for the student, the fact that the provider happens to be religiously affiliated should be no bar to the referral. However, all referrals for services must be provided in a religiously neutral manner. Thus, a MCHB-funded abstinence program should not steer its students toward or away from religiously affiliated referral agencies. When making any type of referral, the MCHB-funded abstinence program should consider only the professional qualifications, availability, accessibility, and the conduct of the referral agency.

(6) Question: A grantee is located in a geographic region in which the population is predominately one particular religious denomination. MCHB-funded abstinence education is available to anyone, regardless of religious denomination. However, due to the nature of the area, most of the students are of a single denomination. Does the fact that most students are of one denomination present a problem?

Answer: MCHB-funded abstinence education grantees may be affiliated with a particular religious denomination. However, the abstinence education must be accessible to the public generally, regardless of the student's religious denomination. Grantees must assure that information about their abstinence education program is broadly disseminated throughout the community, including through public media, such as radio or television, and advertisements in public facilities or areas. Additionally, the program is prohibited from selecting students based on their religious affiliation. No problem is presented, however, where most of the students are of a single denomination due to the fact that the grantee is located in a geographic region in which the population is predominantly that denomination or for reasons unrelated to the grantee's selecting of students based on their religious affiliation (e.g., coincidences, accessibility of the program to a particular population group, comfort level of particular student population group with the educational program).

(7) Question: In teaching an adolescent, in what context, if any, may a MCHB-funded abstinence teacher help the student explore the connection between her religious views, if any, and the issue at hand (i.e., sexual abstinence-until-marriage)?

Answer: During an abstinence class, an adolescent's religious beliefs may arise in two contexts:

- (A) when the adolescent raises the issue of her/his religious beliefs or
- (B) when the teacher believes that it is important for the adolescent to consider a variety of factors (including parental and peer values and moral beliefs) in order to make his/her own decisions responsibly.

In both of these contexts, the key principle is that the MCHB-funded abstinence program must be neutral as to religion. That is, the instruction may not disparage or discourage religion in any way, nor may the instruction engage in any inherently religious activities such as sectarian instruction, worship, prayer, proselytization. Thus, in the first situation, the teacher should acknowledge the importance of the role religious beliefs play in an individual's life, but must refer the student to other sources of counsel outside the classroom (parents, religious leaders, etc.) to explore the substance of the relevant religious beliefs. If the adolescent wishes specific guidance relating to her/his religious beliefs, she/he should be told to discuss the matter with her/his parents or the religious counselor of her/his choice outside of the classroom.

In the second situation, it is important for the teacher to encourage a student to make decisions with reference to the student's own views on appropriate and moral conduct, whether those spring from religious or non-religious beliefs. If, as a result of that discussion, a student requests guidance on religious issues, she/he should be told to discuss the matter with her/his parents or the religious leader of her/his choice outside of the classroom. Under no circumstances may a teacher express a judgment with regard to a student's religious or non-religious beliefs, or seek to change the religious or non-religious beliefs of a student, or in any way favor religious over non-

religious beliefs or vice versa in the context of helping a student explore her/his own moral views. The teacher may wish to explain that the abstinence education class is a government-

sponsored class and, therefore, religious counseling or teaching, while very important to many people, is beyond the scope of the program.

In the classroom, a teacher may note that religious beliefs regarding sexual behavior may play an important role in affecting an individual's views and may permit discussion on this point as long as the teacher does not convey a position. The teacher should suggest that participants consult with their parents or religious leaders for a follow-up discussion on this matter.

- (8) Question: A MCHB-funded abstinence teacher is discussing with adolescents reasons for postponing premarital sexual activity. An adolescent comments that the Bible (or the church) teaches that premarital sexual activity is wrong and cites references. Class participants want to discuss this and ask about other religions' teachings on this topic.
- (a) How should this situation be handled?
- (b) How should the situation be handled if this was a class involving parents and teens together or parents alone, as opposed to adolescents alone?
- Answer: (a) The teacher may acknowledge that many faiths teach that premarital sexual activity is wrong and that an individual's faith may play an important role in making a decision on this matter. It would be inappropriate for the teacher to say or imply that religion is irrelevant to the topic, since this would violate the principles of neutrality with respect to religion. Depending on the time permitted and the level of interest expressed by the adolescents, it is acceptable to explore a variety of religious and nonreligious teachings on the subject of premarital sexual activity, although the teacher may not convey any view as to which one is the better view. The teacher should suggest that further discussion or questions should be addressed to parents and/or clergy.
- (b) If parents express interest on this subject, the teacher may explore a variety of religious and nonreligious teachings on the subject of premarital sexual activity. The teacher may not convey any view as to which one is the better view. Teachers should explain that it is a government-sponsored project and, therefore, religious counseling or teaching, while important to many people, is beyond the scope of the program.

APPENDIX C

Human Subjects

The Department of Health and Human Services (DHHS) regulations for the protection of human subjects provide a systematic means, based on established internationally recognized ethical principles, to safeguard the rights and welfare of individuals who participated as subjects in research activities supported or conducted by the DHHS. The regulations require that applicant organizations establish and maintain appropriate policies and procedures for the protection of human subjects. These regulations, 45 CFR 46, Protection of Human Subjects, are available from the Office for Protection from Research Risks, National Institutes of Health, Bethesda, MD 20892.

The regulations stipulate that an applicant organization, whether domestic or foreign, bears responsibility for safeguarding the rights and welfare of human subjects in DHHS-supported research activities. The regulations define "human subject" as a "living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information." The regulations extend to the use of human organs, tissues, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable state and local law and is not directly regulated by 45 CFR 46.

An applicant organization proposing to conduct non-exempt research involving human subjects must file an Assurance of Compliance with the Office for Protection from Research Risks (OPRR). As part of this Assurance, which commits the applicant organization to comply with the DHHS regulations, the applicant organization must appoint an institutional review board (IRB), which is required to review and approve all non-exempt research activities involving human subjects.

Exempt from coverage by the regulations are activities in which the only involvement of human subjects will be in one or more of the following six categories:

- Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- 2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject.
- 3. Research involving survey or interview procedures, except where all of the following conditions exist: (i) responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects; (ii) the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's

APPENDIX C

financial standing or employability; and (iii) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. All research involving survey or interview procedures is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office.

- 4. Research involving the observations (including observation by participants) of public behavior, except where all of the following conditions exist: (i) observations are recorded in such a manner that the human subjects can be identified, directly or through the identifiers linked to the subjects; (ii) the observations recorded by the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability; and (iii) the research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.
- 5. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- 6. Unless specifically required by statue, research and demonstration projects which are conducted by or subject to the approval of the DHHS, and which are designed to study, evaluate, or otherwise examine: (i) programs under the Social Security Act, or other public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. However, if following review of proposed research activities that are exempt from these regulations under this paragraph, the Secretary of the DHHS determines that a research or demonstration project presents a danger to the physical, mental, or emotional well-being of a participant or subject of the researcher demonstration project, then Federal funds may not be expended for such a project without the written informed consent of each participant or subject.